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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/121,849 07/24/98 GARFIELD

R SCH1237DI

EXAMINER

023599 HM12/0913
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FILING H	
ART UNIT	PAPER NUMBER

1651
DATE MAILED:

23
09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/121,849

Applicant(s)

GARFIELD ET AL.

Examiner

HERBERT J LILLING

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27, 29, 30 and 32-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-13, 15, 16, 20-27, 30, 32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 14, 17, -19 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-13, 15, 16, 20-27, 30, 32 and 33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

1. Receipt is acknowledged of the amendment filed September 04, 2001.

2. Claims 1-27, 29-30 and 32-35 remain present in the instant application.

Claim 28 has been cancelled.

Claim 31 was previously cancelled

3. Applicant has elected Group II, Claims 14, 17, 18, 19 and 29, drawn to a pharmaceutical composition containing at least the following three components (a) a progestin and the species , **progesterone** (b) a nitric oxide synthesis substrate, a nitric oxide donor or both, the elected species is **a nitric acid donor which species is nitroglycerin** and (c) at least one of the ingredients as noted by Claim 14, and (c) **is a cyclooxygenase inhibitor which is aspirin.**

The restriction and election requirement is proper as stated. The arguments have been deemed not to be persuasive. The withdrawal of the non-elected species in view of the rejection based on the generic claim is proper. Applicant's arguments are not appropriate in view of the continuing rejection (as submitted below for the generic claim) of the elected species.

Thus, Claims 1-13, 15, 16, 20, 21, 22-27, 30, 32-33 and 34-35 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions or species.

The restriction and election have been made Final.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 14, 17, 18, 19 and 29 are rejected under 35 U.S.C. 103(a) as obvious over Harrison et al U.S. 5,508,045.

The arguments have been found not to be persuasive in view of the totality of the exceptionally broad pertinent disclosure which would motivate one of ordinary skill to employ the combinations with reasonable expectation of success and predictability to perform as recited:

Harrison et al teaches in columns 21-22 and examples compositions which specifically teaches

processes which employs obvious compositions of nitroglycerin in combination with nitric oxide donors, see column 35 as well as employing the elected species aspirin.

which disclosure would have been prima facie obvious to one of ordinary skill in the art absent unexpected or unobvious results, see the following decisions:

Obviousness does not require absolute predictability (see In re Merck and Company Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); In re Lamberti, 545 F.2d 747, 192 USPQ 278 (CCPA 1976); In re Miegel et al. 159 USPQ 716; and In re Moreton 129 USPQ 288), but only a reasonable expectation of success (see In re Longi 225 USPQ 645; In re Pantzer et al. 144 USPQ 415; and In re Farnham et al. 188 USPQ 365).

The arguments drawn towards the of **process of treating** preeclampsia accompanied or unaccompanied by preterm labor, dysmenorrhea, or functional uterine bleeding or hemorrhaging carry very little weight for the claimed compositions absent a showing of a criticality, unexpected results or data which claimed compositions lack any specific ranges of the admixtures. Thus, it has been considered that the broad disclosure of the reference teaches admixtures compositions which renders the claims unpatentable.

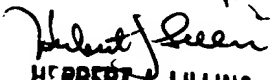
5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is (703) 308-2034 and fax number is (703) 308-4242 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL
(703) 308-2034
Art Unit 1651
September 12, 2001


HERBERT J. LILLING
PATENT EXAMINER
GROUP 1500 ART UNIT 1651